510(K) SUMMARY

NOV 2 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: K/23/85

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

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Contact Person:

Zhai Pei

Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: August 28, 2012

2. Device Name: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic

Ultrasound System

Classification

Regulatory Class: II Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Device Description:

DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, PW-Mode, CW mode, Color-Mode, Color M-Mode, Power/Dirpower Mode, TDI mode, 3D/4D mode,

Elastography or the combined mode (i.e. B/M-Mode). This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 3 MHz to 10.0 MHz.

4. Intended Use:

The DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.

5. Comparison with Predicate Devices:

DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Number
1	Mindray	DC-8/DC-8PRO/DC-8 CV /DC-8 EXP/DC-8S	K113647
2	Mindray	DC-7	K103583 K101041
3	Mindray	DC-T6	K110199
4	Mindray	Z6	K122010
5	SIEMENS	ACUSON S2000	K112596
6	SIEMENS	SONOLINE Antares Ultrasound Imaging System	K050034

They have the similar technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate devices.

6. Non-clinical Tests:

DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. This device has been designed to meet the following standards: IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC

60601-2-37, IEC 62304, IEC 62366,UL 60601-1, ISO14971, UD 2, UD 3 and ISO 10993-1.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



MAR 2 1 2013

Food and Drug Administration 10903 New Hampshire Avenue Document Control Room –WO66-G609 Silver Spring, MD 20993-0002

Shenzhen Mindray Bio-Medical Electronics Co., Ltd. % Mr. Jeff D. Rongero Senior Project Engineer Underwriters Laboratories, Inc. 12 Laboratory Drive Research Triangle Park, NC 27709

Re: K123185

Trade/Device Name: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S

Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYO, IYN, and ITX

Dated: September 27, 2012 Received: September 10, 2012

Dear Mr. Rongero:

This letter corrects our substantially equivalent letter of November 2, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C5-2E	<u>D8-3E</u>
C7-3E	<u>V11-3E</u>
L12-3E	<u>C11-3E</u>
L14-6NE	DE10-3E
L14-6WE	<u>V11-3BE</u>
P4-2E	V11-3WE
D6-2E	<u>L7-3E</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Ms. Lauren Hefner at (301) 796-6881.

Sincerely Yours,

Anhul Doran for

Janine M. Morris

Director

Division of Radiological Health Office of In Vitro Diagnostic

and Radiological Health

Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

K123185

Device Name: DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

510(k) Number (if known):

ndications For Use:
The DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.
Prescription Use X AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health(OIR)
Page 1 of1 (Division Sign Off) Division of Radiological Health Office of in Vitro Diagnostics and Radiological Health
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Diagnostic Ultrasound Indications For Use Format

System:

DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer:

N/A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applicat	ion					Mod	e of Operation	on	
General (Track t Only)	Specific (Track 1 & 3)	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal	2	P	P		P	P	P	Note 1, 2,3, 4,6,7
	Abdominal.	P	P	P	P	P	P	P	Note 1, 2,3, 4,5,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1, 2,3, 4,5,6,7
Fetal Imaging &	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7
Other	Adult Cephalic	P	P	P	P	Р	P	P	Note 1, 2,4,5,6,7
	Trans-rectal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Trans-vaginal	P.	P	Р		P	P	Р	Note 1, 2, 4,6,7
	Trans-urethral								
	Trans-esoph. (non-Card.)								<u></u>
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Musculo-skeletal (Superficial)	P	P	P		P	.P	P	Note 1, 2, 4,6,7
	Intravascular						I		
	Cardiac Adult	P	P	P	P	P	Р	P	Note 1, 2,4,5,6,7
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7
Cardiac	Intravascular (Cardiac)	Π							· .
	Trans-esoph. (Cardiac)						1	ļ	
•	Intra-cardiac								
Peripheral	Peripheral vessel	P	P	P		Р	P	P	Note 1, 2, 4,6,7
vessel	Other (Specify***)	P	P	P		P	P	P	Note 1, 2, 4,6,7

N-new indication: P-previously cleared by FDA: E-added under Appendix E
Additional comments: Combined modes-B+M. PW+B. Color + B. Power + B. PW +Color+ B. Power + PW +B.
Intraoperative includes abdominal, thoracic, and vascular.
**Small organ-breast, thyroid, testes.
•••Other use includes Urology.
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.
Note 2: Smart3D
Note 3:4D(Real-time 3D)
Note 4: iScape
Note5: TDI
Note6: Color M
Note7: Biopsy Guidance
Note8: Elastography
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Division of Radiological Health

Office of in Vitro Diagnostics and Radiological Health

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DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer:

C5-2E

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows: Intended Use:

C	linical Application					Mode	e of Operation	70.	
General (Track I Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
1	Fetal	P	P	P		Р	P	P	Note 1, 2, 4,6,7
	Abdominal	P	P	P		P	P	Р	Note 1, 2, 4,6,
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	Р	P		Р	Р	P	Note 1, 2, 4,6,
	Small Organ (Specify**)								
Fetal imaging & Other		Г							
	Adult Cephalic								
	Trans-rectal		Г						
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)						<u> </u>		
	Musculo-skeletal (Conventional)	P	Р	P		P	P	P	Note 1, 2, 4,6,
	Musculo-skeletal (Superficial)			ļ					
	Intravascular								
	Cardiac Adult							<u> </u>	
	Cardiae Pediatric								
Cardiac	Intravascular (Cardiac)	L				ļ			
	Trans-esoph. (Cardiac)	L	<u> </u>	1_	-				
	Intra-cardiac	_	\vdash		↓		-	 	11 1 2 46
Peripheral	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,6
vessel	Other (Specify***)			1			<u> </u>		
N=new indication	Propositionally cleaned by FDA	E	adde	d under	Append	lix E			
Additional com	ments: Combined modes-B+M.	PW+	B. (Color +	B. Pov	ver + B. F	W +Color+	B. Power +	- PW +B.
*Int	raoperative includes abdominal, th	oraci	c, and	vascul	ar.				
	nall organ-breast, thyroid, testes.								
	Other use includes Urology.								
	1: Tissue Harmonic Imaging. The	fean	ire do	es not u	ise conti	rast agents	·		
	: 2: Smart3D		_						
	3:4D(Real-time 3D)	_							
	e 4: iScape es: TDI					<u> </u>			
	6: Color M								
	7: Biopsy Guidance								
	8: Elastography								

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer:

C7-38

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application					Mode	e of Operation	on	
General (Track Only)	Specific (Track 1 & 3)	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal	P	P	P		P	Р	P.	Note 1, 2, 4.6,7
Abdominal	P	P	P		P	P	Р	Note 1, 2, 4,6,7	
	Intra-operative (Specify*)								
	Intra-operative (Neuro)			<u></u>					
	Laparoscopic			L					
Fetal Imaging &	Pediatric	P	·P	P		P	P	Р.	Note 1, 2, 4,6,7
	Small Organ (Specify**)								
	Neonatal Cephalic				<u> </u>		ļ		
	Adult Cephalic								
	Trans-rectal							ļl	
	Trans-vaginal			<u> </u>	L		<u> </u>		
	Trans-urethral			<u> </u>					
	Trans-esoph. (non-Card.)	L	Ŀ	<u> </u>			<u> </u>		
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)			<u> </u>					
	Intravascular								
	Cardiac Adult					<u> </u>			
	Cardiac Pediatric		<u> </u>				<u> </u>		
Cardiac	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)					ļ		<u> </u>	
	Intra-cardisc			\perp		<u> </u>			
Peripheral	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,6,7
vessel	Other (Specify***)								

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes—B+M. PW+B. Color + B. Power + B. PW+Color+ B. Power + PW+B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Office of In Vitro Diagnostics and Radiological Health

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DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer:

L12-3E

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					Mode	of Operation	תכ	
General (Track i Only)	Specific (Track & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdominal	٩	æ	P		P	P	P	Note 1, 2, 4,6,7
	Intra-operative (Specify*)								
Fetal Imaging & Other	Intra-operative (Neuro)					<u> </u>			
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Small Organ (Specify**)	P	P	P		P	P	Р	Note 1,2, 4,6,7,8
	Neonatal Cephalic	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)			<u> </u>	<u></u>		<u> </u>		
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Intravascular	ļ	1 _						
	Cardiac Adult			l					
	Cardiac Pediatric								
Cardiac	Intravascular (Cardiac)								•
	Trans-esoph. (Cardiac)								
	Intra-cardisc			-					
Peripheral	Peripheral vessel	P	P	P		P	P	Р	Note 1, 2, 4,6,7
vessel	Other (Specify***)								

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes—B+M. PW+B. Color+B. Power+B. PW+Color+B. Power+PW+B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

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Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Office of In Vitro Diagnostics and Radiological Health

51000 K123185

DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer:

L14-6NI

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application					Mode	of Operation	in	
General (Track I Only)	Specific (Track & 3)	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal								
	Abdomina)	P	P.	P	L	, P	P	P	Note 1,2, 4,6,7
•	Intra-operative (Specify*)								
	Intra-operative (Neuro)		•						
	Laparoscopic								
	Pediatric	P	P	P		P	₽	Р	Note 1,2, 4,6,7
,	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,6,7,8
Fetal Imaging & Other	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal						İ		
	Trans-urethral			П					
,	Trans-esoph. (non-Card.)							,	
	Musculo-skelem! (Conventional)	P	P	P		P	P	P	Note 1,2, 4,6,7
	Musculo-skeletal (Superficial)	P	P	Р		Р	P	P	Note 1,2, 4,6,7
	Intravascular				\Box				
	Cardiae Adult								
	Cardiac Pediatric			L					
Cardiac	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac					L			
Peripheral	Peripheral vessel	P	P	P		P	P	P	Note 1,2, 4,6,7
vessel	Other (Specify***)			\		J	1		

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes—B+M、PW+B、Color + B、Power + B、PW + Color + B、Power ÷ PW + B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

****Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: 4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Division of Radiological Health

Office of in Vitro Diagnostics and Radiological Health

51000 K123185

DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer:

L14-6WE

Intended Use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application					Mode	e of Operation	m	
General (Track l Only)	Specific (Track I & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal								10.465
	Abdominal	Р	P	P		P	P	Р	Note 1,2, 4,6,7
	Intra-operative (Specify*)				<u> </u>				
	Intra-operative (Neuro)		L						
. 1///	Laparoscopic			L				<u></u>	
	Pediatric	P	P	P		P	P	P	Note 1,2, 4,6,7
Fetal Imaging & Other	Small Organ (Specify**)	P	P	P		P	P	. Р	Note 1,2, 4,6,7,8
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,6,7
	Adult Cephalic						<u></u>		
•	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)					<u> </u>			
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2, 4,6,7
	Musculo-skeletal (Superficial)	P	P	P		P	P	P.	Note 1,2, 4,6,7
	Intravascular								
	Cardiac Adult								
	Cardiae Pediatric			Ι			<u> </u>		
Cardiac	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)							<u> </u>	<u>. </u>
	Intra-cardiac	L.,							
Peripheral	Peripheral vessel	P	P	P		P	Р	P	Note 1,2, 4,6,7
vessel	Other (Specify***)					1			

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes—B+M. PW+B. Color+B. Power+B. PW+Color+B. Power+PW+B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

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Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

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Note8: Elastography

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Office of in Vitro Diagnostics and Radiological Health

51000 K123185

DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: P

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Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application		1	•		Mod	e of Operation	an .	
General (Track I Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Calor Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic .								
	Fetal								
	Abdominal	P	P	P	P	Р	P	Р	Note 1, 2,4,5,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	Р	P	P	Р	P	Note 1, 2,4,5,6,7
	Small Organ (Specify**)								
Fetal Imaging & Other		P	Ρ.	P	P	P	P	P	Note 1, 2,4,5,6,7
	Adult Cephalic	P	P	Р	P	Р.	Р	P	Note 1, 2,4,5,6,7
	Trans-rectal								
	Trans-vaginal		\Box						
	Trans-urethral								
	Trans-esoph. (non-Card.)				-				
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Cardiac Adult	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7
	Cardiac Pediatric	P	Р	P	P	P	P	P	Note 1, 2,4,5,6,7
Cardiac	Intravascular (Cardiac)				<u> </u>	<u> </u>			
	Trans-esoph. (Cardiac)	<u> </u>	_		-	ļ			
	Intra-cardiac	\vdash		 	-		-	-	·
Peripheral	Peripheral vessel	L			<u> </u>		↓		
vessel	Other (Specify***)			1					

N*new indication: P*previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes—B÷M. PW+B. Color+B. Power+B. PW+Color+B. Power+PW+B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

**Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

(Division Sign Off)

510N K123185

DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: D6-2

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	linical Application					Mod	e of Operation	ភា	
General (Track Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal	P	P	P		P	P	P	Note1,2, 3, 4,6
	Abdominal	P	P	P		P	p	P	Note1,2, 3, 4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric .	P	P	P		P	P	Р	Note1,2, 3, 4,6
Fetal Imaging & N	Small Organ (Specify**)	Ĺ.,		L.,					
	Neonatal Cephalic				Ĺ	<u> </u>			
Other	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal			L	<u> </u>				
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)				L]			
	Intravascular				·				
	Cardiac Adult							1	
	Cardiac Pediatric								
Cardiac	Intravascular (Cardiac)					· ·			
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Peripheral vessel								
ressel	Other (Specify***)								

N=new indication: P=previously cleared by FDA: E=	added under Appendix E
Additional comments: Combined modes-B+M. PW+	B. Color + B. Power + B. PW +Color + B. Power + PW +B.
*Intraoperative includes abdominal, thoracion	, and vascular.
**Small organ-breast, thyroid, testes.	
•••Other use includes Urology.	
Note 1: Tissue Harmonic Imaging. The featu	re does not use contrast agents.
Note 2: SmarUD	
Note 3:4D(Real-time 3D)	
Note 4: iScape	
Note5: TD1	
Nate6: Color M	
Note7: Biopsy Guidance	

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Note8: Elastography

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

51000 K123185

DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S Diagnostic Ultrasound System

Transducer: DS

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					Mode	of Operation) To	
General (Track I Only)	Specific (Track 1 & 3)	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal	Р	P	Р		P	P	P	Note1,2, 3, 4,6
	Abdominal	P	P	P		· P	P	P	Notel,2, 3, 4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal Imaging & Other	Pediatric	P	P	P		P	P	P	Note1,2, 3, 4,6
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic							•	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								*
	Trans-esoph. (non-Card.)								
٠.	Musculo-skeletal (Conventional)	-							
	Mustulo-skeletal (Superficial)					_			•
	Intravascular								
	Cardiac Adult								
	Cardiac Pediatric								
Cardiac	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac) .								
	Intra-cardiac								
Peripheral P	Peripheral vessel							l	
ressel	Other (Specify***)								

N~new indication: P=previously cleared by FDA: E~added under Appendix E
Additional comments: Combined modes-B+M、PW+B、Color ÷ B、Power ÷ B、PW +Color ÷ B、Power ÷ PW +B.
*Intraoperative includes abdominal, thoracic, and vascular.
**Small organ-breast, thyroid, testes.
***Other use includes Urology.
. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.
Note 2: Smart3D
Note 3:4D(Real-time 3D)
Note 4: iScape
Note5: TDI
Note6: Color M
Note7: Biopsy Guidance
Note8: Elastography
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Division of Radiological Health

Concurrence of CDRH, Office of Device Evaluation(ODE)

Office of In Vitro Diagnostics and Radiological Health

510pg 1/123185

Transducer: D8-3E

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

C	linical Application					Mode	e of Operation	n	
General (Track I Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic .								
	Fetal	P	P	P		P	P	Р	Note 1, 2, 3, 4,6
	Abdominal	P	P	P		P	Р	P	Note1,2, 3, 4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	Р	P	Note 1,2, 3, 4,6
Fetal Imaging & Other	Small Organ (Specify**)			\Box					
	Neonatal Cephalic	Г							
	Adult Cephalic								
	Trans-rectal	\Box							
•	Trans-vaginal								
	Trans-urethral	Г							
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	-							
-	Musculo-skeletal (Superficial)	Г							•
	Intravascular								
	Cardiac Adult								•
	Cardiac Pediatric								
Cardiac	Intravascular (Cardiac)					•			
	Trans-esoph. (Cardiac) .						·		
	Intra-curdisc						<u> </u>		
Peripheral	Peripheral vessel								
vessel	Other (Specify***)							J	

N-new indication: P-previously cleared by FDA: E-added under Appendix E
Additional comments: Combined modes-B+M. PW+B. Color + B. Power + B. PW +Color+ B. Power + PW+B.
Intraoperative includes abdominal, theracic, and vascular.
**Small organ-breast, thyroid, testes.
***Other use includes Urology.
. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.
Note 2: Smart3D
Note 3:4D(Real-time 3D)
Note 4: iScape
Note5: TDI
Note6: Color M
Note7: Biopsy Guidance
Note8: Elastography
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Concurrence of CDRH, Office of Device Evaluation(ODE)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

51000 K123185

Transducer: V11-3E

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					Mod	e of Operation) (1)	
General (Track I Only)	Specific (Track 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fctal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
0 0	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	Р	P		P	P	P	Note 1, 2, 4,6,7
	Trans-vaginal	P	P	P		P	P	P	Note 1, 2, 4,6,7
_	Truns-urethral								
	Trans-esoph. (non-Card.)						•		
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravasculor								
	Cardiac Adult								
•	Cardiac Pediatric								
Cardiac	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
-	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel	Other (Specify***)	P	P	P		P	P	Р	Note 1, 2, 4,6,7

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes—B+M. PW+B. Color+B. Power+B. PW+Color+B. Power+PW+B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3: 4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Olvision of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510M K123185

Transducer: C11-3E

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation									
General (Track I Only)	Specific (Track 1 & 3)	В	м	PWD	CWD	Color Doppter	Amplitude Doppler	Combined (specify)	Other (specify)		
Ophthalmic	Ophthalmic										
	Fetal										
	Abdominal	N	N	N		N	N	ĸ	Note 1, 2, 4,6,7		
	Intra-operative (Specify*)										
	Intra-operative (Neuro)										
	Laparoscopie										
	Pediatric	N	N	N		ĸ	N'	N	Note 1, 2, 4,6,7		
	Small Organ (Specify**)	Ŀ									
fetal maging &	Noonatal Cephalic	К	N	N		N	К	N	Note 1, 2, 4,6,7		
Other	Adult Cephalic										
	Trans-rectal	\prod	•								
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Conventional)						_				
	Musculo-skeletal (Superficial)										
	intravasçular .	T									
	Cardiac Adult	N	N	N		N	N	N	Note 1, 2, 4,6,7		
	Cardiae Pediatric	N	N	И		N	И	К	Note 1, 2, 4,6,7		
Cerdiac	Intravascular (Cardiae)										
	Trans-esoph. (Cardiac)										
	Intra-cardiac		\Box								
Peripheral	Peripheral vessel	N	И	N		N	N	N	Note 1, 2, 4,6,7		
ressel	Other (Specify***)										
N-sew izdio	cation: P=previously cleared by FD/	la E-se	ided up	der Аррс	ndix E						
Additional o	omments: Combined modes-B+M.	PW+B	. Colo	+ B. P	ower + I	3. PW +(Color+ B. P	ower + PW +	8.		
	Intraoperative includes abdominal, t	oracic,	and vas	cular.							
•	*Small organ-breast, thyroid, testes.								•		
•	**Other use includes Urology.										
٨	lote 1: Tissue Harmouic Imaging. Th	: feature	does a	ol use co	itrașt ag	cuts.					
1/	lote 2: Smart3D										
	lote 3:4D(Real-time 3D)										
N	lote 4; iScape										
Ь	iou5: TDI										
N	lote6: Color M										
N	lote7: Biopsy Guidance							•			
	lote8: Elastography										

Concurrence of CDRH, Office of Device Evaluation(ODE)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

51000 10123185

Transducer: DE10-JE

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					Mode	of Operation		
General (Track I Daly)	Specific (Track 1 & 3)	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetal	Ñ	×	N		Ñ	N	И	Note 1, 2, 3,4,6
	Abdomizal								•
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopie								
	Pediatric								
1	Small Organ (Specify**)								
Fetal	Neonatal Cephalic								
lonaging & Other	Adult Cephalic								
	Trans-rectal	N	N	N		N	ĸ	N	Note 1, 2, 3,4,6
	Trans-vaginal	N	N	N		N	N	N'	Note 1, 2, 3,4,6
	Trans-ureduel								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								•
	Intravascular								
	Cardiac Adult								
	Cardine Pediatrie	1							
Cardiac	Intravascular (Cordiac)	1							
	Trans-esoph. (Cardiae)	1							
	Intra-cardiac			 	_				
Peripheral	Peripheral vessel	+							
vessel	Other (Specify***)	+-							
			Mad	4		لـــــا			
	cation: P-previously cleared by FDA comments: Combined modes-B+M.	_				B. BM *4	Colore B P	onuer + DW +	D.
	*Intraoperative includes abdominal, th				UWCI F I	2. 7 W 1	- COLON - D. T.	OWEL - FW -	
	*Small organ-breast, thyroid, testes.	ioracic, o	- VE						
	**Other use includes Urology.								
		- C	4000	24 114 2 22					
	Note 1: Tissue Harmonic Imaging. The	: remune	goes a	or use co	no and all				
	Note 2: SmartJD								
	Note 3:4D(Real-time 3D)		•						
	Note 4; iScape								
	Note5: TDI								
	Note6: Color M								
	Note7: Biopsy Guidance								
1	Note8: Elastography								
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Division of Radiological Health

Office of in Vitro Diagnostics and Radiological Health

510pg 15123185

Transducer: V11-3BE

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application					Mode	of Operation		
General (Track I Oxly)	Specific (Truck I & 3)	В	М	PWD	ÇWD	Cotor Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
	Fetai	N	N	N		N	N	Ñ	Note 1, 2, 4,6,7
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)	\top							
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
Fetal	Neonatal Cephalic				- 1				
lmaging & Other	Adult Cephalic								
	Trans-rectal	N	2	N		N	И	N	Note 1, 2, 4,6,7
•	Trans-vaginal	N	N	N		N	N	Ň	Note 1, 2, 4,6,7
	Tracs-victhral								
	Trans-rsoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
. P	Musculo-skeletal (Superficial)								
	Intravascular								
-	Cardiac Adult								
	Cardiac Pediatric								
Cardiac	Intravascular (Cardiac)								
	Truns-esoph. (Cardiac)	\top					-		
	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel	Other (Specify***)	N	N	И		N	N	N	Note 1, 2, 4,6,7
N=pew indi	cation: P-previously cleared by FD	4 E−u	ided uz	der Appe	ndia E				
	comments. Combined modes-B+M.			_		B. PW +	Color+ B. P	ower + PW +	ъ.
	*Intraoperative includes abdominal, t	boneic,	and va	cular.			4	•	
	*Small organ-breast, thyroid, testes.								
•	***Other use includes Urology.								
1	Note 1: Tissue Harmonic Imaging. Th	e feature	does n	ot use co	ga kerin	enu.			
1	Note 2: Smart3D								
1	Note 3:4D(Real-time 3D)								
1	Note 4: iScape								
1	Note5: TDI								
1	Note6: Color M								
1	Note7: Biopsy Guidance								
	Note8: Elastography		_						

Division of Radiological Health

Concurrence of CDRH, Office of Device Evaluation(ODE)

Office of In Vitro Diagnostics and Radiological Health

51000 K123185

Transducer: V11-3WE

Climical Application

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

General (Track I Ozly)	Specific (Track 1 & 3)	В	м	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthelmic	Ophthalmic								
	Fetal	N	N	N		Ñ	N	N	Note 1, 2, 4,6,7
	Abdominal								
	latra-operative (Specify*)		Γ						
	Intra-operative (Neuro)								Maria Cara
	Laparoscopic								
	Podiatric								
	Small Organ (Specify**)								_
Fetal	Neonatal Cephalic								
maging & Other	Adult Cephalic	1							
	Trans-rectal	N	N	И		N	N	N	Note 1, 2, 4,6,7
	Trans-vaginal	N	N	N		N	-к	N'	Note 1, 2, 4.6,7
	Trans-urethral								
	Trans-esoph. (non-Card.)								
1	Musculo-skeletal (Conventional)								
	Museulo-skeletal (Superficial)								
	Intravasçular								
	Cardiac Adult								
f	Cardiac Pediatric					$\overline{}$			
Cardiac	Intravascular (Cardisc)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripticial vessel								
ressel	Other (Specify***)	N	N	·N		N	N	ĸ	Note 1, 2, 4,6,7
V-new indi	cation: P-previously cleared by FD/	\: E=ac	lded un	der Appe	ndix E				
Additional o	omments: Combined modes-B+M.	PW+B	. Color	+B. P	ower + E	3. PW+0	Color+ B. P	ower + PW +	в.
	fatraoperative includes abdominal, the	horacic,	and vas	cular.					
•	*Small organ-breast, thyroid, testes.								
•	**Other use includes Urology.							-	
h	lote 1: Tissue Harmonic Imaging, Th	e feature	does o	ot use con	trast ag	ruts.			
N	lote 2: Smart3D								
١	(ote 3:4D(Real-time 3D)								
1	lote 4: iScape								
7	late5: TDI						******		
1	lote6: Color M								
N	lote7: Biopsy Guidance								
	lote8: Elastography		_						

Division of Radiological Health

Concurrence of CDRH, Office of Device Evaluation(ODE)

Office of in Vitro Diagnostics and Radiological Health

510M K123155

Transducer: L7-31

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation										
General (Track I Only)	Specific (Track _, 1 & 3)	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic	Ophthalmic											
	Fetal				\vdash							
	Abdominal	N	н	N		N ·	N	N	Note 1,2, 4,6,7			
	Intra-operative (Specify*)											
	Intra-operative (Neuro)	\top										
	Laparoscopic											
	Pediatric	К	N.	N.		К	ĸ	ĸ	Note 1,2, 4,6,7			
	Small Organ (Specify**)	N	И.	N		N	N	N.	Note 1,2, 4,6,7			
retal . maging &	Neonatal Cephalic	N	N	И		N	N	N'	Note 1,2, 4,6,7			
Other	Adult Cephalic											
	Trans-rectal						•					
	Trans-vaginal											
	Trans-urethral											
	Trans-esoph. (non-Card.)											
	Musculo-skeletal (Conventional)	N	N	N		N	N	К	Note 1,2, 4,6,7			
	Musculo-skeletal (Superficial)	N	K	N		ĸ	N	N	Note 1,2, 4,6,7			
A	Intravascular											
-	Cardiac Adult											
	Cardiac Pediatric											
Cardiac	Intravascular (Cardine)											
	Trans-esoph. (Cardiac)											
	Intra-cardiec											
eripheral	Peripheral vessel	N	N	N		N	N	N	Note 1,2, 4,6,7			
, p.,	Other (Specify***)			•								

N=new indication: P=previously cleared by FDA: E=added under Appendia E	
Additional comments: Combined modes-B+M. PW+B. Color + B. Power + B. PW +Color- B. Power + PW +B.	
*Intraoperative includes abdominal, thoracic, and vascular.	
**Small organ-breast, thyroid, testes.	
•••Other use includes Urology.	
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.	
Note 2: SmartD	
Note 3:4D(Real-time 3D)	
Note 4: iScape	
Note5: TD1	
Note6: Calor M	
Note7: Biopsy Guidance	
Note8: Elastography	
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